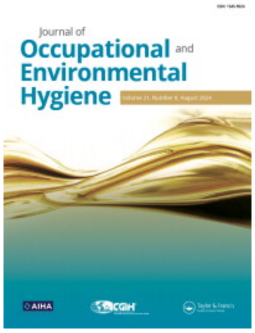

Journal of Occupational and Environmental Hygiene

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/uoeh20

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To cite this article: Edward M. Fisher, Rebecca T. Streeter, Kent C. Hofacre, Lee Ann Greenawald, N. Katherine Yoon, Jhy-Charm Soo & Patrick H. Keyes (2024) Assessment of glove stretch and storage temperature on fentanyl permeation: Implications for standard test methods and PPE recommendations, Journal of Occupational and Environmental Hygiene, 21:8, 529-538, DOI: 10.1080/15459624.2024.2346294

To link to this article: https://doi.org/10.1080/15459624.2024.2346294

JOURNAL OF OCCUPATIONAL AND ENVIRONMENTAL HYGIENE
2024, VOL. 21, NO. 8, 529–538
https://doi.org/10.1080/15459624.2024.2346294

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REPORT

Assessment of glove stretch and storage temperature on fentanyl permeation: Implications for standard test methods and PPE recommendations

Edward M. Fisher[a], Rebecca T. Streeter[a], Kent C. Hofacre[b], Lee Ann Greenawald[a], N. Katherine Yoon[a], Jhy-Charm Soo[c], and Patrick H. Keyes[b]

[a]National Personal Protective Technology Laboratory, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Pittsburgh, Pennsylvania; [b]Battelle, Columbus, Ohio; [c]Department of Biostatistics, Epidemiology and Environmental Health Sciences, Jiann-Ping Hsu College Public Health, Georgia Southern University, Statesboro, Georgia

ABSTRACT

The National Institute for Occupational Safety and Health recommends the use of nitrile gloves with a minimum thickness of 5.0 ± 2.0 mil [0.127 ± 0.051 millimeters] in situations where it is suspected or known that fentanyl or other illicit drugs are present. However, there is limited data available on fentanyl permeation through gloves. Current test methods used to measure fentanyl permeation do not consider the effect of glove fit and flexion. Furthermore, first responders need to have PPE readily available in the field, and storage conditions may affect the protective performance of the gloves. The objective of this study was to evaluate the effects of glove stretch and storage temperatures on glove durability and barrier performance against fentanyl. Nine nitrile glove models previously shown to be resistant to fentanyl permeation were selected for this investigation. These nine models were stretched 25% in one linear direction, to consider glove fit and flexion, and tested against fentanyl hydrochloride permeation. Additionally, four of the nine glove models were stored at 48 °C, 22 °C, and −20 °C, and evaluated for tensile strength, ultimate elongation, and puncture resistance after up to 16 wk of storage and fentanyl permeation after up to 8 wk of storage. At least one sample for six of the nine tested models had maximum permeation over the test method fail threshold when stretched. The tested storage temperatures showed no effect on glove tensile strength, ultimate elongation, and puncture resistance. The findings of this study can be used to inform PPE recommendations, with consideration to storage practices and proper sizing for first responders with potential exposure to fentanyl and other illicit drugs. The results of this study can be used to assess the need for new standard test methods to evaluate the barrier performance of gloves and shelf-life determination with consideration to glove fit.

KEYWORDS
Dermal; first responder; nitrile; opioids

Introduction

Personal protective equipment (PPE) is the last line of defense for first responders when exposed to illicit drugs such as fentanyl and carfentanil (Howard and Hornsby-Myers 2018; Greenawald et al. 2020). The National Institute for Occupational Safety and Health (NIOSH) has developed PPE recommendations for respiratory, dermal, face and eye, and hand protection based on the level of exposure to illicit drugs. For hand protection, nitrile gloves with a minimum thickness of 5 ± 2 mil (0.127 ± 0.051 millimeters) are recommended when illicit drugs are expected to be present. Double gloving or thicker gloves are also recommended for moderate exposures when small amounts of illicit drugs are visible (NIOSH 2020). However, there are limited data available for glove barrier performance against opioids and standard test methods to assess fentanyl permeation through gloves.

Greenawald et al. (2020) adapted ASTM International D6978-05R19, “Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs” to assess fentanyl and carfentanil hydrochloride (HCl) solution

CONTACT Edward M. Fisher EFisher@cdc.gov National Personal Protective Technology Laboratory, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, 626 Cochrans Mill Road, Pittsburgh, PA 15236.

Supplemental data for this article can be accessed online at https://doi.org/10.1080/15459624.2024.2346294. AIHA and ACGIH members may also access supplementary material at http://oeh.tandfonline.com.

permeation through nitrile gloves. Manufacturers have also adapted this method to provide barrier performance data for Food and Drug Administration (FDA) clearance to claim fentanyl protection; however, they use fentanyl concentrations representative of the therapeutic mixes used in healthcare (ASTM International 2005a; FDA 2024). These performance assessments may not be representative of the potential exposures to illicit opioids experienced by first responders. Greenawald et al. used a 20-fold increase of fentanyl (1 mg/mL) compared to therapeutic concentrations and tested the barrier performance of gloves against carfentanil to better understand glove performance within the context of illicit drug exposures. Nitrile gloves that were consistent with NIOSH recommendations for hand protection during exposure to illicit drugs did not demonstrate fentanyl or carfentanil permeation. However, there are concerns that the current methods used to assess glove performance do not appropriately mimic in-use conditions and variables such as temperature, flexion, stretch, and pressure (Klingner and Boeniger 2002; Wallemacq et al. 2006; Phalen et al. 2014).

The stretching of glove material has been shown to affect chemical permeation (Phalen et al. 2014), and thus the size and fit of gloves may influence their barrier performance against fentanyl and other synthetic opioids. Current barrier performance tests do not consider fit and flexion, leading to uncertainty in the effectiveness of workplace protection. ASTM D6978-05R19 specifies that samples to be tested for permeation be cut from the palm or cuff of each medical glove and placed between the two chambers of the test cell. This test configuration does not mimic the stretch that may occur when gloves are worn or the dynamic motion of hand movement (Griffin et al. 2019). Glove size selection is often guided by comfort or availability, which may result in the use of snug-fitting gloves (Mylon et al. 2014). Hand flexion and motion have been shown to further increase glove stretch (Griffin et al. 2019). It should be noted that some manufacturers may provide more precise hand measurement recommendations for the selection of the proper glove size for their specific product, but many manufacturers omit sizing recommendations on glove packaging.

In addition to glove size, glove storage temperature may influence the physical properties (tensile strength, ultimate elongation, and puncture resistance) and barrier performance of gloves. In fact, ASTM methods for medical gloves include specifications to promote accelerated aging using elevated temperatures (ASTM International 2016b, 2019a). The exposure to elevated temperatures, including 50 °C, 78 °C, and 100 °C, for specified periods is used to determine the quality of the material and shelf-life of gloves based on changes to the physical properties of glove materials. After thermal exposure, the physical properties of gloves, such as tensile strength, ultimate elongation, and detection of holes, are measured. Fentanyl permeation resistance is not one of the required tests for medical gloves, and a correlation between physical properties and barrier performance has yet to be demonstrated.

The effect of temperature on glove performance is important when considering possible storage conditions of first responder PPE. Literature describing current PPE storage practices for first responders is sparse; however, some first responder departments may likely keep boxes of gloves in their vehicles (e.g., police car, ambulance, fire truck) to ensure that gloves are readily available (Richards 2006). Temperatures inside of parked and unoccupied vehicles have been shown to exceed accelerated aging temperatures specified in ASTM methods (ASTM International 2016b, 2019b), within hours (Grundstein et al. 2010). Some departments supply PPE at the beginning of each shift in kits that are attached to duty belts worn by first responders or in carry-on bags that are placed in the vehicle during each shift (DPP 2003; Richards 2006). PPE carried on the person of first responders are not likely to be exposed to conditions that are not tolerable by the first responder; therefore, accelerated aging from exposure to extreme temperatures in this scenario is unlikely. Placing PPE in carry-on bags may limit long-term exposure to extremely high and low temperatures; however, gloves and other PPE left in vehicles for a few minutes may be exposed to temperature fluctuations (McLaren et al. 2005).

This study builds on the investigation of fentanyl permeation of disposable gloves reported by Greenawald et al. (2020). The purpose of this study was to evaluate the effects of glove stretch on barrier performance against fentanyl and storage temperatures on barrier performance against fentanyl and glove durability. The hypotheses for this study are that (1) gloves that are stretched will demonstrate reduced barrier performance against fentanyl permeation compared to non-stretched gloves and (2) gloves stored in 48 °C and −20 °C will demonstrate a reduction in the efficacy of barrier performance against fentanyl compared to gloves stored at ambient temperature and (3) gloves stored in 48 °C and −20 °C will demonstrate a reduction in durability (i.e., physical properties performance) of gloves compared to gloves stored at ambient temperature.

Materials and methods

Glove models

The nitrile gloves used in this study are the same models and lot numbers used in the Greenawald et al. (2020) investigation and were purchased at the same time from the same suppliers. Table 1 shows the nine glove models used to assess the effect of stretch on fentanyl permeation and includes the glove ID given in Greenawald et al. the manufacturer sizing, and the storage recommendations. Only nitrile glove models that passed the fentanyl permeation assessment, which was conducted on unstretched gloves by Greenawald et al. were selected. Four nitrile glove models, which were a subset of the nine nitrile glove models tested for permeation when stretched, were randomly selected to assess the effect of storage temperature on fentanyl barrier performance. All gloves tested came from one production lot; however, separate boxes of gloves from the lot were used for each storage temperature.

Fentanyl permeation assessment

Stretched gloves

The gloves used to assess the effect of stretch on glove permeation were pulled from the same boxes used in the Greenawald et al. (2020) investigation. Gloves were stretched 25% to determine the effect of glove fit and flexion on fentanyl permeation. This level of stretch was estimated from the difference in circumference from upper to lower tolerance values of nitrile glove sizes as permitted by ASTM D6319-19 (Table 2) and the change in hand circumference during various dynamic motions such as finger spread and fist clenching (ASTM International 2019b; Griffin et al. 2019). For example, small and medium gloves can have a 25% and 21% difference in circumference, respectively when considering the width tolerances allowances in ASTM D6319-19. Griffin et al. (2019) reported changes in the palmar spread of roughly 15% when comparing measurements along the most prominent crease of the palm when phalanges were together and when splayed.

Glove samples were cut from the palm of the glove using a 3.8- × 10-cm rectangular die and press. The dye-cut sample formed a loop, which was then cut to form a 3.8- × 20-cm strip. The inside and outside orientation of the glove was maintained so that the fentanyl challenge solution was in contact with the outside surface of the glove. The glove sample swatch was then secured around two posts of the custom-made stretching apparatus. A 25% elongation was achieved by turning two threaded rods that were located between the posts (Figure 1). Turning the threaded rods caused the swatch-supporting posts to separate in a controlled and repeatable manner, stretching the glove in one direction—laterally across

Table 1. Summary of selected glove models for testing.

Glove ID[a]	Manufacturer claims fentanyl protection[a]	Glove sizing instructions provided on packaging	Storage recommendations provided on packaging
G4[b,c]	Y	N	Store in cool, dry place. Open box should be shielded from exposure to direct sunlight, intense artificial light, x-ray machines, and other sources of ozone.
G5[c]	Y	N	Protect from freezing; avoid excessive heat. Keep dry. Shield from sunlight, fluorescent lighting, and x-rays.
G6	Y	N	Store in a dry, cold, well-ventilated area. Do not store above 104 °F (40 °C). Shield open box from direct sunlight, fluorescent lighting, and x-rays.
G7[c]	Y	N	Open boxes should be shielded from direct sun, x-rays, fluorescent lighting, and ozone.
G8	N	N	Store in a cool, dry place. Open box should be shielded from exposure to direct sunlight, intense artificial light, x-ray machines, and other sources of ozone.
G9	N	N	Store in a dry, ventilated area. Avoid direct sunlight, fluorescent lighting, heat, and moisture. Do not store above 100 °F (38 °C).
G10	Y	N	Store in temperatures lower than 40 °C. Avoid exposure to direct sunlight, intense artificial light, x-ray machines, and other sources of ozone.
G11	N	Y	None
G12[c]	N	N	None

[a]As reported by Greenawald et al. (2020).
[b]Tested in both stretched and unstretched (relaxed) configuration.
[c]Included in glove storage testing.

Table 2. Glove palm circumference differences based on ASTM D6319-19 hand size designations.

ASTM D6319-19 size designation	x-small	small	unisize	medium	large	x-large
ASTM width requirement (mm)	70	80	85	95	110	120
Tolerance (mm)	±10	±10	±10	±10	±10	±10
Circumference (mm)[a,b]	140	160	170	190	220	240
Circumference upper tolerance (mm)[a]	160	180	190	210	240	260
Circumference lower tolerance (mm)[a]	120	140	150	170	200	220
Difference in circumference (%)[a,c]	29	25	24	21	18	17

[a]Calculated from the width requirements of ASTM D6319-19 size designations.
[b]Calculated as two times the width.
[c]Calculated as the absolute value of the difference between the upper and lower tolerances divided by the average of the upper and lower tolerances.

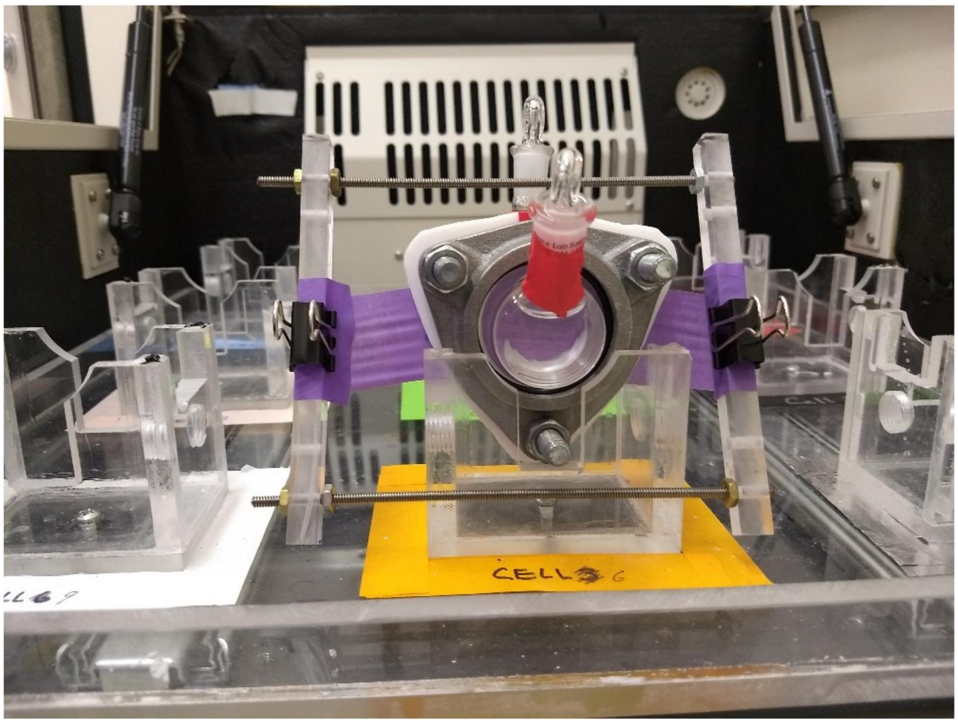

Figure 1. Permeation cell and apparatus used to maintain stretching the glove 25% for the duration of the fentanyl permeation testing.

the width of the palm. This stretching mechanism maintained the fixed stretch while the sample was placed in the permeation cell and throughout the permeation test. The thickness of each sample relaxed and stretched, was measured as required per ASTM F739-12. The sample thickness was measured to at least the nearest ±20 μm (per ASTM 6978-05R19, Section 7.1.3) using an Ames Comparator (Model BG2600-1-04).

After stretching, the test sample was secured in the permeation cell, and testing was initiated. Three samples of each glove model were tested for fentanyl permeation. One glove model (G4) was tested for fentanyl permeation in a relaxed or unstretched state to compare with the permeation rates reported by Greenawald et al. (2020).

Stored gloves

Three temperatures, −20 °C, 22 °C, and 48 °C, were selected to span a range of potential field storage conditions that PPE may be exposed to when placed in a first responder's vehicle or on their duty belt at the beginning of each shift. The temperatures do not represent the cold and hot extremes that may occur inside unoccupied emergency vehicles. Gloves, in their original box, were stored in target conditions in an environmentally controlled laboratory operating at 22 ± 3 °C, in environmental test chambers at −20 °C (humidity recorded but not controlled), and at 48 ± 3 °C. After the gloves were stored for the specified time, gloves from the top, middle, and bottom of the box were pulled, and glove samples were excised using a 5.1 cm-diameter die and press. The inside and outside orientation of the glove was maintained so that the fentanyl challenge solution was in contact with the outside surface of the glove, as it would be in actual use. Fentanyl permeation of three samples of the four glove models was measured after 1, 4, and 8 wk for gloves stored at 48 °C and −20 °C, but only 8 wk for the 22 °C.

Test parameters and conditions

ASTM D6978-05R19 Procedure A was adapted for the fentanyl permeation testing in this study and conducted in the same laboratory under identical conditions as detailed in Greenawald et al. (2020). Briefly, glove samples (both those that were stretched and those that were stored at 48 °C, 22 °C, and 18 °C were placed into the glass permeation cells (Part # PTC 600; Pesce Lab Sales, Inc; Kennett Square, PA) and secured to the rotating platform of a temperature-controlled incubator (Innova model 4000; New Brunswick Scientific) sustained at 35 ± 2 °C. Purified, deionized water (18 mL) was added to the collection reservoir. A 0.1-mL sample of the collection water was collected using a disposable 1-mL pipette and designated t_0 = 0 min. 18 ml fentanyl HCl (1 mg/mL), diluted in Milli-Q water (Millipore Sigma, Burlington, MA) was added to the donor reservoir, and the shaker set to 150 rpm was activated to provide agitation for mixing of the fluids in the cell. A 0.1 mL aliquot was sampled from the collection reservoir every 30 min over the 4-hr test duration, for a total of eight samples collected per swatch.

The fentanyl concentration of both collection samples and any challenge solution samples were quantified using a Battelle-developed liquid chromatograph mass spectrometer-mass spectrometer (LC/MS/MS) method as previously described in Greenawald et al. (2020).

Glove durability assessment

Tensile strength and ultimate elongation

Tensile strength and ultimate elongation tests were performed simultaneously using an Instron single-column machine (Instron, Series 5940, Model 5943, Norwood, MA), following ASTM D412-16, "Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension" (ASTM International 2016a). A Tippmann Die Cut Press machine (Tippmann Clicker, Model CL-K07, Fort Wayne, IN) with Die C was used to cut the palms into dumbbell-shaped samples. The samples were cut from a single layer of the glove and cut lengthwise. Triplicate measurements of glove thickness were collected from three locations along the sample using a Checkline digital micrometer (Electromatic Equipment CO., Inc, model MTG-D 2154, Cedarhurst, NY) with an 80-gram weight attached, following ASTM D3767-03, "Standard Practice for Rubber-Measurements of Dimensions" (ASTM International 2014). All were measured to the nearest 10 µm and recorded. The dumbbell-shaped glove samples were placed into the sample grips of the Instron and stretched at a rate of 500 ± 50 mm/min. The data was recorded using BlueHill 3 (Instron, Norwood, MA) software.

Puncture test

Puncture tests were performed using an Instron 5943 (Instron, Series 5940, Model 5943, Norwood, MA) machine following ASTM F1342-05, "Standard Test Method for Protective Clothing Material Resistance to Puncture," test Method A (ASTM International 2005b). Rectangular samples were cut by hand from the palm of the glove and mounted into the support assembly so that they were taut. The probe was programmed to have a uniform rate of 50.8 cm/min. The testing machine was then set in operation and set to calculate the maximum load (Newtons, ± 0.4 N) and extension (mm, ± 0.1 mm) at the breakpoint of each sample. If a sample was not punctured, the maximum load was logged, and the extension was recorded as ≥20 mm.

Data analysis

Fentanyl permeation

The permeation rate of fentanyl was calculated in accordance with ASTM F739-12 (ASTM International 2012) and reported for each sample if there was detectable fentanyl (0.001 µg/cm^2/min) in the collection reservoir. To meet the ASTM D6978-05R19 and F739-12 minimum performance requirements, a glove specimen must not have a permeation rate above 0.01 µg/cm^2/min within the 240-min test. The number of samples for each glove model that had detectable permeation and permeation exceeding the ASTM-defined threshold of 0.01-µg/cm^2/min were compared to the results reported for the same glove model/lot reported in Greenawald et al. (2020).

Durability

Analysis of variance (ANOVA) was used to examine the main effect of temperature, the main effect of time (weeks), and the two-way interaction on durability measures. ANOVA has been repeatedly found to be robust to deviations from normality (e.g., Schmider et al. 2010; Blanca Mena et al. 2017). Further, Levene's tests were performed on each outcome variable to test homogeneity (tensile strength and ultimate elongation were found not significant $p > 0.05$, and puncture had significance $p < 0.05$).

Results

Fentanyl permeation

Stretched gloves

A 25% stretch of glove material resulted in an average reduction in thickness of 11% across all glove models. The maximum permeation rate through each sample of gloves stretched by 25% is presented in Table 3. Eight of the 27 samples had measurable permeation. Six replicates exceeded the maximum permeation rate threshold criterion for this study of 0.01 $\mu g/cm^2/min$, which occurred either at the 30-min or 60-min collection time point, well short of the 4-hr requirement. Three samples of G4 tested in a relaxed state showed no measurable permeation.

Stored gloves

The average maximum permeation rate for the four glove models (G4, G5, G7, G12) in all tested storage conditions was below 0.001 $\mu g/cm^2/min$ for up to 240 min. No measurable fentanyl permeation (<0.001 $\mu g/cm^2/min$) occurred for 83 of the 84 test samples. One G6 glove sample had a maximum permeation rate of 0.0017 $\mu g/cm^2/min$ at the 240-min sample time.

Tensile strength, ultimate elongation, and puncture resistance

Table 4 shows descriptive statistics for each durability measurement for the gloves. In cold temperatures, tensile strength, ultimate elongation, and puncture decreased after 16 wk. In ambient conditions, elongation decreased over time. In ambient temperature, puncture slightly increased, and tensile strength did not change over time (tensile strength decreased after 8 wk but increased again at 16 wk). In hot temperatures, elongation decreased but puncture increased over time. Finally, tensile strength increased at 8 wk but decreased at 16 wk (although tensile strength at 16 wk was higher than at 0 wk). The effect of temperature (F statistic = 2.060, $p > 0.05$) and time (F statistic = 1.247, $p > 0.05$) as well as the interaction effect of temperature and time (F statistic = 1.489, $p > 0.05$) were not statistically significant for tensile strength. For ultimate elongation and puncture, the main effect of time was statistically significant (F statistic = 44.362, $p < 0.001$ for ultimate elongation and F statistic = 3.100, $p < 0.05$ for puncture). The main effect of temperature and the interaction effect of temperature and time were not statistically significant for ultimate elongation and puncture. A table statistical analysis for the durability measurements for the gloves can be found under supplemental information.

Discussion

This study examined the effect of stretch and storage conditions on the barrier performance of gloves against fentanyl in addition to the effect of storage conditions on the durability of gloves. The assessment of stretched gloves for fentanyl protection demonstrated a highly variable barrier performance for the tested gloves and supported the hypothesis that gloves that are stretched will demonstrate lower barrier performance against fentanyl permeation compared to gloves in an unstretched state. The results of the study show that the tested storage conditions did not diminish the durability and barrier performance of the tested gloves, which did not support the hypothesis. The findings of this study along with comparisons to current glove standard test methods, manufacturer sizing and storage instructions, and workplace conditions

Table 3. Average thickness and maximum permeation rate for gloves stretched 25%.

	Thickness (mil)		Maximum Permeation Rate ($\mu g/cm^2/min$)		
Glove Model/Lot	Unstretched	Stretched	Sample 1	Sample 2	Sample 3
G4/L1	3.3	3.0	**0.41**	0.008[a]	<0.001
G5/L2	4.9	4.4	**0.073**	<0.001	<0.001
G6/L1	5.8	5.3	**2.4**	<0.001	<0.001
G7/L1	6.8	6.2	<0.001	<0.001	<0.001
G8/L2	4.5	3.9	<0.001	<0.001	<0.001
G9/L2	2.4	2.2	<0.001	**1.7**	<0.001
G10/L1	5.5	4.8	<0.001	<0.001	**15**
G11/L1	2.5	2.2	0.002[a]	**0.72**	<0.001
G12/L1	3.2	2.6	<0.001	<0.001	<0.001

[a]Detectable permeation.
Bold numbers-exceeds the ASTM D6978-05R19 specified threshold of 0.01 $\mu g/cm^2/min$.

Table 4. Summary statistics for durability measurements of gloves.

		Period of storage						
		0 weeks		8 weeks		16 weeks		
Measurements	Storage Temp. (°C)	Mean	SE[a]	Mean	SE	Mean	SE	Overall Mean
Tensile Strength (N)	−20	17.6	1.1	18.5	0.9	16.5	0.8	17.5
	21	17.3	1.1	17.7	1.1	20.0	1.1	18.4
	48	17.9	1.1	20.2	1.1	19.7	0.8	19.3
Ultimate Elongation (mm)	−20	862.9	20.6	761.3	16.1	651.1	25.6	758.4
	21	848.6	30.1	791.4	17.9	670.8	23.4	770.3
	48	878.1	26.4	766.7	34.3	685.2	27.6	767.7
Puncture (N)	−20	8.2	0.5	8.1	0.5	7.9	0.1	8.1
	21	8.5	0.5	9.3	0.5	7.8	0.1	8.5
	48	8.3	0.4	10.1	0.7	8.8	0.1	9.1

[a]SE = Standard Error.

and PPE needs of first responders suggest an opportunity to improve glove performance assessments and use recommendations, including proper sizing and storage.

Stretched gloves

Fentanyl permeation >0.01 μg/cm^2/min was evident in 6 of 27 samples of the stretched gloves. All glove samples were selected from the same boxes of gloves used in the Greenawald et al. (2020) study, which found no detectable permeation for 81 samples representing 3 lot numbers. These results show a difference in performance between stretched and unstretched gloves. Unstretched gloves that passed the modified ASTM D6978-05R19 for fentanyl as conducted in Greenawald et al. may not provide an equivalent barrier performance when in use due to stretching caused by the fit of the glove and hand movement. Others have found that glove movement and stretch have changed permeation profiles for gloves using other challenge agents. Phalen et al. (2014) found that simulated movement using whole gloves decreased the breakthrough time by an average of 18% and increased the average steady-state permeation rate of ethanol by 18% for all gloves tested. The simulated movement, achieved by inflating and deflating the glove with air, was designed to represent the stretch of gloves during hand extension and flexion. Likewise, Colligan and Horstman (1990) found that a chemotherapeutic drug permeated through a flexed latex exam glove at twice the rate of the static glove. The permeation of chemicals through stretched gloves when using static a static stretch method as demonstrated in this study and other investigations that have used dynamic stretch methods reported in the literature raises a concern about the effect of glove fit on the barrier performance of disposable gloves despite the difference in permeation kinetics between the two stretch methods.

Stored gloves

This study found no statistically significant changes in the durability and fentanyl barrier performance of gloves related to the tested storage temperatures. Studies that examine the effect of storage conditions on glove permeation by chemicals are lacking. Moreover, there are no requirements for barrier performance assessment after thermally accelerated aging; thus, the barrier performance of gloves to chemicals after exposure to storage conditions is not well characterized. Unlike barrier performance testing, durability tests (ultimate elongation and tensile strength) are conducted after accelerated aging per the specifications of ASTM D6319-19 and ASTM D7160-16. Nitrile gloves that meet the requirements of these standard methods are shown to have maintained physical property performance after heat exposure which would be consistent with our findings. Accelerated aging is conducted at 70 °C for 166 h or at 100 °C for 22 h for ASTM D6319-19 and 50 °C for 90 days for ASTM D7160-16. The temperatures of the standard test methods are higher than the warmest temperature tested in this study and exceed the hottest storage temperatures (40 °C and 38 °C) provided by the manufacturers of gloves used in this study (Table 1).

Others, such as Esmizadeh et al. (2021), have demonstrated the durability of nitrile gloves after exposure to hot and cold temperatures. After exposure to 85 °C for 30 min each for 20 cycles, the nitrile gloves demonstrated no significant change in tensile strength and ultimate elongation but measured a decrease in cross-link density for up to five treatment cycles. However, chemical permeation was not assessed for this study. Another investigation (Nalin et al. 2021) measured the effect of cold storage temperatures on glove durability to better understand the expected levels of protection for medical staff in extreme Arctic cold (−34.4 to −40 °C). Nitrile gloves failed the durability assessment, determined by water leakage when stored in −80 °C but passed the durability tests conducted after glove exposure to −20 and −50 °C. Neoprene gloves were shown to fail durability testing after storage at −50 °C, demonstrating possible differences in material performance (Nalin et al. 2021). Only one nitrile glove model was tested, and chemical permeation was not assessed, but the results for the experiments conducted on gloves exposed to −20 °C support the findings reported for the four glove models tested in this investigation. It should be noted that the effect of storage temperatures on the barrier performance of gloves has not been determined for stretched gloves, which would better simulate wear. There was a statistically significant difference in performance for ultimate elongation over time; however, the performance of the glove samples for ultimate elongation under all tested conditions surpassed the specifications for nitrile gloves (ASTM International 2019b).

Implications for glove standards and use recommendations

The results of this study identify critical knowledge gaps associated with the barrier performance of gloves. Proper glove fit is difficult to determine and current glove standards for glove size designations and performance evaluations have limitations. Further, different wearer preferences on fit may affect the level of stretch attained by a glove during use. ASTM barrier tests use samples excised from gloves and not whole glove samples (particularly excluding the fingers and thumb that are often of different thickness than the sampled areas for permeation testing). This approach precludes the assessment of glove fit on protection against any chemical agent (ASTM International 2005a). Furthermore, the specifications for glove sizing permit a range of glove circumferences for each size designation (Table 2), which can change the fit of a particular-sized glove depending on the brand. A particular glove model could qualify for multiple designations (e.g., small/medium, medium/large) based on the overlap in glove width requirements among size designations specified in ASTM D6319-19, further complicating the selection of appropriate fitting gloves.

Coupled with a lack of specific sizing instructions from manufacturers (Table 1), the barrier performance of gloves for end users is uncertain. Therefore, test standards should be developed to evaluate whole gloves with consideration of glove fit. Standard glove sizing designations and glove manufacturing sizing recommendations should be further evaluated to determine if the expected barrier performance of gloves can be enhanced with improvements to glove fit. First responders can consider the use of double gloves or thicker gloves as recommended by NIOSH when illicit drugs are visible (NIOSH 2020). Double gloving has been shown to improve the barrier performance against chemical permeation compared to single glove use (Banaee and Hee 2019); however, there are no studies that evaluated the efficacy of double gloves against fentanyl permeation, though improved performance would be expected.

The work environment of first responders presents a unique challenge and PPE, including gloves, must be readily available. Temperatures inside of unoccupied vehicles can surpass the accelerated aging challenge temperature specified in ASTM D6319-19 and ASTM D7160-16 within hours, and storing gloves in vehicles for long periods can potentially expose gloves to conditions that can exceed these temperatures. Likewise, unoccupied vehicles can reach extreme cold temperatures depending on the climate. These temperatures would not be compatible with the manufacturer storage recommendations (e.g., protect from freezing, do not store above 38 °C, avoid extreme temperatures) listed in Table 1. First responders should avoid storing gloves in unoccupied vehicles or within areas of the vehicles without climate control (trunk or other storage compartments on the exterior of the vehicle).

The practice of supplying PPE to personnel before each shift is one approach to limit glove exposure to extreme temperatures. Gloves carried on duty belts would likely only be exposed to temperatures that are tolerable by the user and are not likely to reach temperatures that cause accelerated aging or exceed manufacturer storage recommendations. Gloves placed in bags and stored in the vehicle at the beginning of each shift would also reduce exposure to extreme temperatures; however, first responders should be cognizant of the potential for vehicles to reach temperatures that exceed manufacturer recommendations when the vehicle is unoccupied.

The findings reported here suggest that nitrile glove models can maintain barrier performance and durability for conditions that are likely to occur when following the above practices and manufacturer storage recommendations.

Limitations

Despite the efficient barrier performance and the negligible change in the durability of the glove models under the various storage conditions evaluated in this study, caution should be used in the interpretation of the results, as this study had several limitations. Only a limited sample number of four glove models were evaluated for the effect of storage conditions. More models of gloves need to be evaluated to assess model-to-model differences. Only samples of gloves and not entire gloves were used to assess permeation, and the uniaxial glove stretch was used to assess the effect of fit and flexion and does not represent the dynamic nature of glove movement and stretch while in use. Post-storage fentanyl permeation tests were conducted under the temperature and relative conditions per the requirements of the ASTM D6978-05R19 method and not conducted under temperatures that are likely experienced during field use. The ASTM methods for tensile strength, ultimate elongation, and puncture resistance were conducted under ambient laboratory conditions and not the conditions required of the ASTM method. However, the durability of gloves (tensile strength, ultimate elongation, and puncture resistance) for all storage conditions was evaluated under the same conditions on the same day for each storage timepoint, allowing for a relative comparison of the performance of gloves stored under the tested conditions. Finally, this study used ASTM methods to evaluate glove performance and the results were discussed within the context of glove performance as evaluated by ASTM methods. These findings may not apply to other standards.

Conclusions

The results of this study, which demonstrate a decrease in fentanyl barrier performance of gloves when stretched, and similar findings reported in the literature, support the need for standard test methods that consider the effect of fit on the barrier performance of gloves. Proper fit of PPE is important to ensure the highest level of protection. As gloves are one of the most widely used PPE, test methods to help inform the proper fit of gloves could have a large impact on the protection of first responders, healthcare personnel, agricultural workers, and other occupational groups that rely on gloves for protection.

Our results showed no change in the durability and fentanyl barrier performance for gloves stored under temperatures that would not be compatible with most manufacturer storage recommendations; therefore, the expected performance of the tested glove models should be maintained when manufacturer storage recommendations are followed.

These findings should not be used to justify storing gloves outside of manufacturer recommendations. Only permeation of fentanyl HCl was evaluated in this study and these findings may not apply to other agents of concern encountered by first responders. Additionally, this study did not assess the performance of gloves stored under the temperature extremes that may occur inside unoccupied emergency vehicles. Glove storage and use guidance are needed to help ensure that the gloves will provide the expected levels of protection for first responders. Avoiding the storage of gloves in unoccupied vehicles can help limit glove exposure to extreme temperatures and temperatures that promote accelerated aging. Safety officers should check with manufacturers to determine if PPE field storage practices are suitable to maintain expected glove performance and emphasize the need for appropriately sized gloves.

Acknowledgments

The authors would like to thank National Personal Protective Technology Laboratory staff members Selcen Kilinc-Balci, Matt Horvatin, and Jonisha Pollard for their reviews of this paper.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health (NIOSH) and the Centers for Disease Control and Prevention (CDC). Product and company names are provided for identification purposes only and do not imply endorsement by the CDC.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Data availability statement

The data will be available on the NIOSH Data and Statistics Gateway once cleared by NIOSH.

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